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The Honorable Sherry R. Fallon
J. Caleb Boggs Federal Building
844 N. King Street, Unit 14 – Room 6100
Wilmington, DE 19801-3555

VIA E-FILING & HAND DELIVERY
REDACTED - PUBLIC VERSION

Re: *Orexo AB and Orexo US, Inc. v. Actavis Elizabeth LLC*
C.A. No. 14-829-SLR-SRF

Dear Judge Fallon:

Orexo submits this letter in advance of the October 1 discovery conference. Orexo seeks an order requiring that Actavis produce (and obtain and produce if necessary) raw materials samples used in the accused Actavis ANDA product as well as samples of intermediates from various stages of manufacture. Incontrovertible evidence shows that Actavis had the requested samples [redacted] but refused to produce them. Actavis should not be permitted to avoid discovery by using up the samples it was obligated to produce and then argue it no longer has them.

The Requested Samples Are Relevant And Actavis Should Be Ordered To Produce Them

The samples in question are relevant. The patents in this case[1] require specific relationships between materials in the claimed formulations: The '996 patent claims a tablet with particles of buprenorphine ***presented at*** (claim 1) or ***adhered to*** (claim 2) the surfaces of carrier particles. (D.I. 54-1, '996 pat. claims). The '330 patent claims a tablet with particles of buprenorphine ***presented upon*** the surfaces of carrier particles, where the buprenorphine is ***in contact with, but not in the same particle*** as citric acid. (D.I. 54-2, '330 pat. claims).

Orexo requested samples of (1) raw materials used to make Actavis's ANDA product (i.e., that meet the specifications in Actavis's ANDA), and (2) raw materials actually used to make Actavis's ANDA product (i.e., that were actually used in manufactured batches of ANDA product) (Ex. 1, 11/18/14 Orexo Request Nos. 17-18) to assist with its infringement analysis.

[1] U.S. Patent Nos. 8,454,996 ("the '996 patent") and 8,940,330 ("the '330 patent").

Request 17 more broadly seeks raw material that meets specification while Request 18 seeks the lot (batch) actually used to make the ANDA product. (See Ex. 2, 9/10/15 Letter at Ex. A for raw material list).

The raw materials are needed for at least two reasons. ***First,*** they are needed as reference materials. Each raw material can be characterized and then used as a reference to identify and compare the location of materials relative to each other in Actavis's tablets[2] to assess whether the above listed claim limitations are met. ***Second,*** blending tests with these samples can show that certain particles "adhere" as required by some asserted patent claims and other relationships between particles.[3] Orexo also requested intermediate samples of Actavis's ANDA product at different stages of manufacture to analyze the structure of Actavis's product. (Ex. 1, 11/18/14 Orexo Request No. 19). Intermediates after various mixing steps in Actavis's manufacturing process can show adherence between particles (one claim requirement) results and is present in Actavis's final product. Obtaining raw materials and intermediates from Actavis, among other things, avoids arguments regarding the representative nature of samples.

The requested sample discovery is basic and probative of infringement. Actavis should be ordered to produce the requested raw material and intermediate samples forthwith.

Actavis Had A Duty To Preserve Sample Evidence In Its Possession

Actavis should not be allowed to avoid production by arguing it does not have raw material and intermediate samples. As shown below, Actavis has (or had) the samples. First, Actavis has begrudgingly over time suggested it might provide some but not all the requested raw materials. Second, Actavis's documents show it had ***all*** the requested samples after Orexo made its sample requests.

Orexo requested samples on November 18, 2014. (Ex. 1, Orexo Requests, excerpt). But Actavis repeatedly refused to produce them. (Ex. 4, 12/18/14 Actavis objections to Request Nos. 17-19). In April 2015 and again in June, Actavis refused to produce raw materials (they did not say they did not have them). (Ex. 5, 4/29/15 Letter excerpt p. 2; Ex. 6, 6/19/15 Letter excerpt p. 6). Regarding intermediate materials Actavis changed positions over time (alleging in April it

[2] Actavis agreed to provide samples of finished product, but still has not produced them. Orexo is currently waiting for Actavis to obtain a DEA (government) export license for controlled substances to ship the buprenorphine containing samples to Orexo's expert. A similar license will be needed for shipment of the buprenorphine active ingredient. Obtaining the necessary licenses can take 2 or more months, requiring that the license process begin promptly to have a chance of meeting the expert report schedule even as the parties currently propose it be revised. (Ex. 3, Proposed amended schedule).

[3] The '996 patent teaches that mixing materials in certain ways for a sufficient amount of time can lead to adherence between particles of those materials. (D.I. 54-1, '996 pat. col. 7, ll. 13-20).

did not have them and then in June stating it was investigating their availability). *Id.* On September 4 Actavis agreed to produce 2 of the [redacted] raw materials used in its ANDA product (showing Actavis had samples even though it refused to provide them earlier). (Ex. 7, 9/4/15 Letter excerpt p. 3). And on September 11 Actavis said it is "investigating" whether it has samples of naloxone (which it should have done months earlier) but still refused to produce samples of all [redacted] materials. (Ex. 8, 9/11/15 Letter).[4] Actavis continues to refuse to produce raw materials like buprenorphine and [redacted], which the claim language addressed above highlights, is central to any infringement analysis.

Amazingly, while refusing to produce samples after Orexo served requests, ***documents show that Actavis had in its possession samples of all raw materials and intermediates for its generic Zubsolv® product.***[5] [redacted].[6]

Actavis also objected to the amount (50 grams) of each sample Orexo requested as excessive. [redacted]

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[4] Selected production of 2 or 3 of [redacted] (or other narrow subset of) raw materials used in Actavis's ANDA product is not sufficient.

[5] As background, Orexo's Zubsolv® product is available in five dosage strengths, which represent the ratio of the two active ingredients, buprenorphine and naloxone (1.4mg/0.36mg, 2.9mg/0.71mg, 5.7mg/1.4mg, 8.6mg/2.1mg and 11.4mg/2.9mg). (Ex. 9, FDA website). Actavis's ANDA No. 206258 seeks to market two strengths (1.4mg/0.36mg and 5.7mg/1.4mg).

[6] [redacted]

[redacted] Nor has Actavis provided anything other than conclusory lawyer argument that providing the raw materials (or intermediates) is unduly burdensome. And, Orexo advised it could consider accepting smaller quantities if Actavis disclosed what it had. (Ex. 2).

Actavis had possession of samples that were the subject of pending document requests and had a duty to preserve them for production. *Wagner v. Sea Esta Motel*, No. 13-81-RGA, 2014 WL 4247731 (D. Del. Aug. 26, 2014) (duty to preserve evidence that plaintiffs requested be preserved). Actavis is a sophisticated company involved in a large number of Hatch-Waxman (ANDA) cases. As such, Actavis knew or should have known before this lawsuit commenced in June 2014 that active ingredient, raw material and intermediate samples were central to this lawsuit and was obligated to retain samples for production in this case. *Magnetar Techs. Corp. v. Six Flags Theme Park Inc.*, 886 F. Supp. 2d 466, 480 (D. Del. 2012) (duty to preserve evidence begins when litigation is pending or reasonably foreseeable).

Under these circumstances, Actavis should be ordered to produce all requested samples forthwith, and if it failed to preserve them, Actavis should be ordered to provide a complete explanation why they were not preserved.

At Minimum Actavis Should Be Ordered To Obtain Representative Samples For Orexo

If Actavis did not preserve samples, at minimum Actavis should be ordered to assist Orexo in obtaining them. Actavis had all requested raw materials in its possession while Orexo's sample requests were pending. Under these circumstances, Actavis should be ordered to purchase and produce the samples in question forthwith.

Actavis's argument that it no longer has samples does not absolve it of the obligation to preserve and produce relevant evidence. On September 10, Orexo asked if Actavis would assist in obtaining samples from suppliers. (Ex. 2). Actavis refused. (Ex. 8). At this stage, the Court should order Actavis to produce representative samples to Orexo, or have Actavis's suppliers ship samples directly to Orexo's expert. (Ex. 2). That is the minimum corrective action needed to cure Actavis's failure to preserve evidence.

In summary, Orexo requests that the Court order Actavis to (1) produce the requested raw material and intermediate samples forthwith, (2) obtain raw materials it does not possess and produce them to Orexo's experts forthwith, and (3) explain any failure to preserve samples in its possession during the pendency of this case.[7]

[7] Orexo does not address its items 2 and 3 from the September 8, 2015 letter to the Court because Actavis made a representation regarding its invalidity positions that satisfied item 2, and stated it would produce the document at issue in item 3. Likewise, Orexo provided the confirmation Actavis sought in Actavis's issue 2 and the documents Actavis sought in issue 3. Orexo therefore considers both parties' issues 2 and 3 resolved.

Respectfully,

/s/ Derek J. Fahnestock

Derek J. Fahnestock (#4705)

DJF/dla
Enclosures
cc: Clerk of the Court (by hand, w/encls.)
All Counsel of Record (by CM/ECF and email, w/encls.)